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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,035	12/22/2004	Sandra De Meyer	TIP0014 US	7001

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,035	DE MEYER ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,2,5-8 and 11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 12 October 2005. Applicant elects Group II, claims 3, 4, 9, and 10, without traverse. Applicant elects a species of HIV protease mutation, 4T, with traverse.

The traversal is on the grounds that the claimed mutant HIV strains all share common features, including that they all contain one point mutation of HIV and that they all correlate to a fold change in susceptibility or resistance of an HIV viral strain towards at least one protease drug. Applicant's traversal regarding the species election is persuasive. The requirement for species election is withdrawn.

It is noted that the Applicant has elected claims directed to a method and thereby lost the right to rejoinder of the product and process claims under *In re Ochiai*.

Claims 1-20 are pending. Claims 1, 2, 5-8 and 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 3, 4, 9, and 10 are examined in the instant application.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: the attorney who replied to the restriction requirement is not on the record. Please update any changes to the power of attorney.

Specification

The abstract of the disclosure is objected to because it contains the title. Correction is required. See MPEP § 608.01(b).

The title of the invention is objected to because it contains the word "new." The following title is suggested: Mutational Profiles in HIV-1 Protease Correlated with Phenotypic Drug Resistance.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 9 and 10 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for determining the susceptibility to or effectiveness of a protease inhibitor for HIV strains with mutations at positions 41 and/or 70 in the protease region, does not reasonably provide enablement for determining the susceptibility or effectiveness of other HIV drugs and other viral drugs in viral strains containing drug-resistant mutations at positions other than 41 and 70. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is a method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant HIV strain, or for evaluating a change in the viral drug susceptibility, comprising: (i) collecting a sample from an HIV-infected patient; (ii) determining whether the sample comprises a nucleic acid encoding HIV protease having at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E; (iii) correlating the presence of said at least one mutation of step (ii) to a change in effectiveness of said protease inhibitor or in viral drug susceptibility.

The guidance presented in the specification is limited to the detection of drug-resistant mutations at positions 41 and 70 in HIV protease. It is well known in the art that HIV is highly evolutionary and develops a wide spectrum of escape mutants (Shafer, 1999) towards not only protease inhibitors but also drugs acting at different sites in an HIV particle, such as reverse transcriptase inhibitors and fusion inhibitors (Parikh, 2000). Due to this unpredictable nature, one skilled in the art would not be able

to assess the susceptibility for all HIV drugs using only the two point mutations provided in the instant claims and specification.

Furthermore, the phrase "viral drug" encompasses a wide range of compounds acting on all viruses. The specification does not provide the drug-resistance mutation profile for any viruses other than HIV. One skilled in the art cannot use the instant invention for other viral drugs because the mutations at positions 41 and 70 are specific for HIV but not every virus. Considering the lack of data or working examples in the specification, the broad scope of the claims, and the complex and unpredictable state and nature of the art, Applicant has not provided sufficient information to enable those skilled in the art to practice the claimed method for all viral drugs without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4, 9, and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by Craig *et al.* (1998).

Claims 3, 4, 9, and 10 read on a method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant

HIV strain, comprising: (i) collecting a sample from an HIV-infected patient; (ii) determining whether the sample comprises a nucleic acid encoding HIV protease having at least one mutation selected from 41S, 41T, 41I, 41K, 41G and 70E; (iii) correlating the presence of said at least one mutation of step (ii) to a change in effectiveness of said protease inhibitor or in viral drug susceptibility.

Craig *et al.* teaches a method for the analysis of HIV protease variants in relation to effectiveness protease inhibitor. This method is based on the correlation between the phenotype, protease inhibitor susceptibility, and the genotype, DNA sequence, of virus isolates obtained from patients after therapy with an HIV protease inhibitor. Viruses are considered resistant if they showed a fourfold or greater increase in IC_{50} relative to the baseline isolate. The sensitivity of the virus isolate to protease inhibitor is measured routinely as a quality control in the drug sensitivity assay. See page 1612. At the same time, DNA extracted from patient samples is sequenced and compared to the clones in the database to determine whether there is mutation and which position the mutation is located. See Figure 1. Craig *et al.* specifically teaches that the 41K mutation is associated with reduced sensitivity to the protease inhibitor, Nelfinavir. See page 1616.

Thus, the instant invention is anticipated by Craig *et al.*

Remarks

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Humphrey, Ph.D.
Patent Examiner
12 December 2005

JEFFREY STUCKER
PRIMARY EXAMINER